



USSN: 10/772,020

Applicant: SCHRIER *et al.*

Attorney Docket: 1-2000.537 US D2

Centre for Applied Microbiology and Research  
&  
European Collection of Cell Cultures

This document certifies that Virus  
(Deposit Ref. V00012608 ) has been accepted as a patent deposit,  
in accordance with  
The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on 26<sup>th</sup> January 2000

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No. FS33819

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

TO

INTERNATIONAL FORM

AKZO NOBEL NV  
VELPERWEG 76  
6824 BM ARNHEM  
THE NETHERLANDS

NAME AND ADDRESS  
OF DEPOSITOR

|  |   |
|--|---|
| <b>I. IDENTIFICATION OF THE MICROORGANISM</b>  |   |
| Identification reference given by the<br>DEPOSITOR:<br><br>CAV (CAA 319)   | Accession number given by the<br>INTERNATIONAL DEPOSITARY AUTHORITY:<br><br>V00012608   |
| <b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>  |   |
| The microorganism identified under I above was accompanied by: <div style="margin-top: 10px;"> <input checked="checked" type="checkbox"/> A scientific description         </div> <div style="margin-top: 10px;"> <input type="checkbox"/> A proposed taxonomic designation         </div> <p>(Mark with a cross where applicable)</p> |   |
| <b>III. RECEIPT AND ACCEPTANCE</b>   |   |
| This International Depository Authority accepts the microorganism identified under I above,<br>which was received by it on 26 <sup>th</sup> January 2000 (date of the original deposit) <sup>1</sup>   |   |
| <b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>   |   |
| The microorganism identified under I above was received by this International<br>Depository Authority on (date of the original deposit) and<br>A request to convert the original deposit to a deposit under the Budapest Treaty<br>was received by it on (date of receipt of request for conversion)                                   |   |
| <b>IV. INTERNATIONAL DEPOSITARY AUTHORITY</b>  |   |
| Name: Dr P J Packer<br><br>Address: ECACC<br>CAMR<br>Porton Down<br>Salisbury SP4 0JG  | Signature(s) of person(s) having the power<br>to represent the International Depository<br>Authority or of authorized official(s):<br><br>Date: <i>P. J. Packer</i> 30/1/00 |

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depository authority was acquired

## APPENDIX 3

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BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

AKZO NOBEL NV  
VELPERWEG 76  
6824 BM ARNHEM  
THE NETHERLANDS

## VIABILITY STATEMENT

Issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following pageNAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY OF STATEMENT  
IS ISSUED

|   |   |
|---|---|
| I. DEPOSITOR  | II. IDENTIFICATION OF THE MICROORGANISM   |
| Name: AKZO NOBEL NV<br><br>Address: VELPERWEG 76<br>6824 BM ARNHEM<br>THE NETHERLANDS   | Accession number given by the<br>INTERNATIONAL DEPOSITARY AUTHORITY:<br><br>V00012608<br><br>Date of the deposit or of the transfer:<br>26 <sup>th</sup> January 2000 |
| II. VIABILITY STATEMENT   |   |
| The viability of the microorganism identified under II above was tested<br>on <sup>2</sup> . On that date, the said microorganism was<br><div style="display: flex; flex-direction: column; align-items: flex-start;"> <div style="display: flex; align-items: center; margin-bottom: 10px;"> <input checked="" type="checkbox"/> <sup>3</sup> <div style="margin-left: 10px;">viable</div> </div> <div style="display: flex; align-items: center;"> <input type="checkbox"/> <sup>3</sup> <div style="margin-left: 10px;">no longer viable</div> </div> </div> |   |

- 1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).
- 2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.
- 3 Mark with a cross the applicable box.

|  |   |
|--|---|
| IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED <sup>4</sup>  |   |
| <p><u>CAV (CAA 319) - ACCESSION NUMBER: V00012608</u></p> <p>INOCULATION OF MDCC - MSB1 CELLS WITH THE VIRUS AND SERIALY DILUTED. THE CELLS WERE OBSERVED FOR 2 WEEKS FOR CPE.</p> |   |
| V. INTERNATIONAL DEPOSITARY AUTHORITY  |   |
| <p>Name: Dr P J Packer<br/>ECACC CAMR<br/>Address: Porton Down<br/>Salisbury<br/>Wiltshire<br/>SP4 0JG</p>   | <p>Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):</p> <p>Date: 30/5/00 P.J.P.</p> |

4 Fill in if the information has been requested and if the results of the test were negative.

## Certificate of Analysis

**Product Description**            CAV (CAA 319)  
**Accession Number**            V00012608

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**Test Description:**            Determination of TCID<sub>50</sub> of Chicken Anaemia Virus CAA-319 as supplied by AKZO Nobel

**Acceptance Criterion/Specification:**    MDCC-MSB1 cells were either inoculated with the test sample or left uninoculated to act as negative controls. The cells are examined microscopically for the presence absence of cytopathic effects (CPE). All negative controls must show no CPE. The viral Titre in the test sample is calculated as per Reed and Muench by analysis of CPE in test cells inoculated with a serial dilution of virus supernatant.

**Date:**                        06/04/00

**Result:**

|                    |   |
|--------------------|---|
| Negative Control:  | Negative                                |
| CPE seen after :   | 4 passages                              |
| TCID <sub>50</sub> | $10^{-6} \times 10^{-6.37} = 10^{6.37}$ |
| Test Sample:       | Viable                                  |
| Overall Result:    | PASS                                    |

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**Test Description:**            The Detection of Mycoplasma by Isolation on Mycoplasma Pig Serum Agar and in Mycoplasma Horse Serum Broth.  
SOP QC/MYCO/01/02

**Acceptance Criterion/Specification:**    All positive controls (*M. pneumoniae* & *M. orale*) must show evidence of mycoplasma by typical colony formation on agar plates. Broths are subcultured onto Mycoplasma Pig Serum Agar where evidence of mycoplasma by typical colony formation is evaluated. All negative control agar plates must show no evidence of microbial growth.  
The criteria for a positive test result is evidence of mycoplasma by typical colony formation on agar. A negative result will show no such evidence.


**Test Number:**    20830

**Date:**                        08/05/00

**Result:**

|                   |          |
|-------------------|----------|
| Positive Control: | Positive |
| Negative Control: | Negative |
| Test Result:      | Negative |
| Overall Result:   | PASS     |

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Authorised by..........ECACC, Head of Quality...11.15/00... Date

## Certificate of Analysis

**Product Description**                      CAV (CAA 319)  
**Accession Number**                      V00012608

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**Test Description:**                      Detection of Mycoplasma using a Vero indicator cell line and Hoechst 33258 fluorescent detection system.  
SOP QC/MYCO/07/05

**Acceptance Criterion/Specification:** The Vero cells in the negative control are clearly seen as fluorescing nuclei with no cytoplasmic fluorescence. Positive control (*M. orale*) must show evidence of mycoplasma as fluorescing nuclei plus extra nuclear fluorescence of mycoplasma DNA. Positive test results appear as extra nuclear fluorescence of mycoplasma DNA. Negative results show no cytoplasmic fluorescence.

**Test Number:**    20830

**Date:**                      08/05/00

**Result:**

|                   |          |
|-------------------|----------|
| Positive Control: | Positive |
| Negative Control: | Negative |
| Test Result:      | Negative |
| Overall Result:   | PASS     |

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**Test Description:**                      Detection of bacteria and fungi by isolation on Tryptone Soya Broth (TSB) and in Fluid Thioglycollate Medium (FTGM). SOP QC/BF/01/02

**Acceptance Criterion/Specification:**                      All positive controls (*Bacillus subtilis*, *Clostridium sporogenes* and *Candida albicans*) show evidence of microbial growth (turbidity) and the negative controls show no evidence of microbial growth (clear).  
The criteria for a positive test is turbidity in any of the test broths. All broths should be clear for negative test result.

**Test Number:**    20830


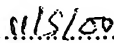
**Date:**                      08/05/00

**Result:**

|                   |          |
|-------------------|----------|
| Positive Control: | Positive |
| Negative Control: | Negative |
| Test Result:      | Negative |
| Overall Result:   | PASS     |

---

\*\*\* End of Certificate \*\*\*

Authorised by..........ECACC, Head of Quality.......... Date



## Certificate of Mailing under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Signature

Diane Payne  
Typed or printed name of person signing Certificate

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**Applicant: Schrier *et al.***  
**Serial No: 10/772,020**  
**Customer No.: 31846**  
**Attorney Docket: I-2000.537 US D2**

Receipt acknowledged of the following documents in the above-identified application:

Response to Office Action of November 8, 2005 (9 pages)  
ECACC accession no: 00020304 (6 pages)  
ECACC accession no: V00012608 (6 pages)  
Self-addressed stamped post card (1)